REMARKS

The Applicants have cancelled Claims 1, 40, and 41 without prejudice, amended Claims 2, 4, 7-10, 17, and 42, and added new Claims 48-52 to more particularly point out and distinctly claim the subject matter that the Applicants regard as their invention. Support for the current amendments to the claims and for the new claims can be found throughout the instant Specification, including in the original claims. Further support for new Claim 48 can be found in the bridging paragraph between Pages 5 and 6, Page 7, lines 3-12, line 24 of Page 19 through line 32 of Page 21, line 18 of Page 23 through 4 of Page 24, and in Figure 2 of the instant Specification. Additional support for new Claim 49 can be found on lines 23-25 of Page 5 of the instant Specification. Further support for new Claim 50 can be found on lines 14-19 of Page 4 of the instant Specification. No new matter has been entered. Claims 2-39 and 42-52 remain for consideration.

Election/Restriction

The Examiner has withdrawn claims 40-47 as being directed to a non-elected invention under 37 CFR 1.142(b) and MPEP § 821.03 because these claims were filed after the Applicants received an action on the merits.

The Applicants file this amendment along with a Request for Continued Examination (RCE). Therefore, the Applicants respectfully request that the Examiner examine Claims 42-52 along with the remaining claims.

The Amendments to the Claims Do Not Introduce New Matter

The Examiner asserts that Claim 1 and the claims that are either directly dependent upon Claim 1 and/or are ultimately dependent upon Claim 1 contain new matter under 35 U.S.C. § 132 and are not in compliance with 35 U.S.C. § 112, first paragraph.

The Applicants respectfully traverse the Examiner's objections and rejections. However, the Applicants have amended the claims to more particularly point out and distinctly claim the subject matter that the Applicants regard as their invention. The

Examiner's objections under 35 U.S.C. § 132 and the rejections under 35 U.S.C. § 112, first paragraph should now be moot.

In view of the above and foregoing reconsideration and withdrawal of the objections under 35 U.S.C. § 132 and the rejections under 35 U.S.C. § 112, first paragraph are respectfully solicited.

The Claimed Invention is Definite

The Examiner has rejected Claims 1-9, 11-14, 16, 18-25, 27-29, 31-33, 35-37 and 39 under 35 U.S.C. § 112, second paragraph. The Examiner asserted that the original Claim 1 was vague and indefinite because, the Examiner asserts that the bounds of the HVT unique long and repeat regions and the unique short region of are MDV are undefined. The Examiner further asserts that there are multiple long regions and multiple short regions present within HVT and MDV, respectively. The Examiner further asserts that the regions of the chimeric virus should be identified with appropriate sequence identification numbers.

The Applicants respectfully traverse the Examiner's rejection. The Applicants have amended the claims to more particularly point out and distinctly claim the subject matter that they regard as their invention. The present invention is particularly claimed and is neither vague nor indefinite.

The Applicants respectfully point out that it is well-established in the field of MDV and HVT that there is only one specific "unique long region" in HVT and MDV, and only one specific "unique short region" in HVT and MDV. In addition, there are only a single pair of long repeats termed, "terminal repeat long" and "internal repeat long" respectively, and only a single pair of short repeats termed, "terminal repeat short" and "internal repeat short" respectively. Consistently, this is the nomenclature employed by Kingham *et al.*, [*J. of Gen. Vir.* **82**: 1123-1135 (2001), *see e.g.*, Table 1] cited by the Examiner. Indeed, Kingham *et al.* state in the bridging sentence between the first two columns of Page 1123:

> "HVT and MDV are both avian alphaherpesviruses. Their genomes consist of two distinct regions, L and S, that are composed of unique long (U_L) and unique short (U_S) sequences bounded by inverted repeats. "

Significantly, Kingham *et al.* contrast the genomic evolution of these two "unique" regions, thereby further indicating that they presume that the skilled artisan readily comprehends the precise metes and bounds of these defined regions of MDV and HVT.

In addition, the written description requirement does not require the disclosure of the nucleotide sequences of well-defined regions of DNA obtained from virions that are well known in the art. Indeed, the Federal Circuit citing the PTO Guidelines states that the written description requirement can be met by:

> "'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ...'" [*Enzo Biochem Inc. v. Gen-Probe Inc.*, 63USPQ2d 1609-1618 (2002)], and "that the written description requirement is satisfied by the patentee's disclosure of such 'descriptive means as words, structures, figures, diagrams, formulas, etc. that fully set forth the claimed invention.'" [*Id.*, at 1617, citations omitted].

In the present case, the instant Disclosure sets forth the claimed invention by providing ample identifying characteristics of the claimed recombinant avian herpesviruses to precisely define the invention.

In view of the above and foregoing reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph is respectfully solicited.

The Claims are Novel

The Examiner has rejected Claims 1-3, 5-7, 9, 11, 13, 18, 20, 24, 25, 28, 29, 32, 33, 36, and 37 under 35 U.S.C. § 102(b) asserting that they are anticipated by Cochran *et al.*, U.S. Patent No. 5,965,138. The Examiner asserts the product disclosed in U.S. Patent No. 5,965,138 appears to be identical or so similar that it is indistinguishable from the product claimed by the applicants specifically citing Example 19 of U.S. Patent No. 5,965,138.

The Applicants respectfully traverse the Examiner's rejection of the Claims under 35 U.S.C. § 102. The claimed invention is not anticipated by U.S. Patent No. 5,965,138.

In order to anticipate a claim the cited reference must teach **every element** of the claim. Moreover, Section 2131 of the MPEP quotes the Federal Circuit as holding:

> "'t]he identical invention must be shown in as **complete detail** as is contained in the ... claim' *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed.Cir. 1989)" [emphasis added].

In the present case U.S. Patent No. 5,965,138 does not disclose all of the elements of the novel recombinant avian herpesviruses of the present invention. Due to the presence of both the unique long region of HVT and the unique short region of MDV, both the claims and disclosure of U.S. Patent No. 5,965,138 indisputably cover the species of recombinant avian herpesvirus of the present invention. However, U.S. Patent No. 5,965,138 does not anticipate the present invention because it does not specifically disclose a recombinant avian herpesvirus that is made up of the unique long region from HVT, the unique short region from MDV, and the repeat regions from HVT; and optionally, can further comprise one or more foreign genes.

This critical distinction becomes apparent when Figure 2 of the instant Specification is compared with Figure 19 of U.S. Patent No. 5,965,138 (which was specifically cited by the Examiner). Figure 2 of the instant Specification is a diagram depicting the construction of a recombinant avian virus of the present invention, NAHV (295-01) from six subgenomic clones, which are listed in the Table below. Example 19 of U.S. Patent No. 5,965,138, discloses a recombinant chimeric virus (S-HVY-145), constructed from six subgenomic clones, which are also listed in the Table below [*see* Column 61, lines 19-29 of U.S. Patent No. 5,965,138]. As is evident, the recombinant avian herpesvirus specifically cited by the Examiner differs from that of the present invention by only the last sub-genomic clone at the 3' end of the two constructs.

COMPARISON OF CONSTRUCTS

Sub-Genomic Clones	Instant Disclosure Figure 2 295-01	U.S. 5,965,138 Example 19 (Column 61, lines 25-29) S-HVY-145
407-32.2C3	✓	✓
172-07.BA2	✓	✓
407-32.5G6	✓	✓
407-32.1C1	✓	✓
989-72.8#1	✓	
739-27.16		✓

Hence, the difference between the two recombinant avian herpesviruses lies within the difference between sub-genomic clone 989-72.8#1 of the present invention and 739-27.16 of U.S. Patent No. 5,965,138. Sub-genomic clone 739-27.16 is defined on Column 37, lines 13-34 of U.S. Patent No. 5,965,138. More particularly, Column 37, lines 27-34 specifically indicate that the short internal repeat regions of MDV are included in S-HVY-145. Therefore, the recombinant avian herpesvirus of U.S. Patent No. 5,965,138 includes the short internal repeat regions of MDV.

In direct contrast, sub-genomic clone 989-72.8#1 of the present invention is defined as comprising the short repeat regions of HVT on Page 21, lines 17-32 of the instant Specification. Therefore, the recombinant avian herpesvirus of U.S. Patent No. 5,965,138 does not include every element of recombinant avian herpesvirus of the present invention. Since S-HVY-145 is as close to the recombinant avian herpesvirus of the present invention as was exemplified in U.S. Patent No. 5,965,138, the present invention is not anticipated by U.S. Patent No. 5,965,138.

In view of the above and foregoing reconsideration and withdrawal of the rejection under 35 U.S.C. § 102 (b) is respectfully solicited.

The Present Invention is not Obvious

The Examiner has rejected Claims 1-39 under 35 U.S.C. § 103(a). The Examiner asserts that the present invention is obvious over Cochran *et al.*, United States Patent No. 5,965,138 and Kingham *et al.* [Journal of Virology, May 2001, Vol. 82, 1123-1135]. The Examiner asserts that United States Patent No. 5,965,138 taught recombinant chimeric viruses comprising the unique long region of HVT and the unique short region of MDV. The Examiner also asserts that Kingham *et al.* taught the complete sequence of HVT. The Examiner concludes by asserting that one of ordinary skill in the art being familiar with United States Patent No. 5,965,138 and Kingham *et al.* would not have anticipated any unexpected results.

The Applicants respectfully traverse the Examiner's rejection of the Claims under 35 U.S.C. § 103(a). The claimed invention is not obvious over U.S. Patent No. 5,965,138, in view of Kingham *et al.* As indicated above, the present invention discloses a novel recombinant avian herpesvirus that is made up of the unique long region from HVT, the unique short region from MDV, the repeat regions from HVT and optionally, one or more foreign genes.

A priori, the skilled artisan would have predicted that an HVT/MDV recombinant virus would best protect against Marek's disease if the repeat regions that are naturally contiguous with the unique short region of MDV were included in the chimeric virus, since this would provide additional MDV antigens. However, unexpectedly, the present Inventors found that this was not true. Rather, the most stable and effective recombinant avian herpesviruses comprises the unique long region from HVT, the unique short region from MDV, and all of the repeat regions from HVT. Indeed, as evidenced by Tables 3, 6, and 8 the recombinant avian herpesvirus of the present invention proved to be significantly more efficacious than the standard HVT and Rispen's vaccines against a live Marek's disease challenge, whether the recombinant avian herpesvirus encoded an antigen from a third virus or not. Similarly, when the recombinant avian herpesvirus of the present invention encoded additional foreign viral antigen(s), *i.e.*, ILT glycoproteins, or

NDV, the resulting vaccines were also effective (*see* Tables 5 and 7 of the instant Disclosure).

Indeed, the unexpected superiority of the specific species of the novel avian virus claimed by the present invention could not have been predicted from either U.S. Patent No. 5,965,138 or Kingham *et al.*, either when taken alone or in combination. Therefore, the present invention is not obvious in view of either U.S. Patent No. 5,965,138 or Kingham *et al.*

In view of the above and foregoing reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully solicited.

No additional fees are believed to arise due to this filing, however, if any additional fees are required, the Commissioner is hereby authorized to charge the required fees to Deposit Account No. 19-0365.

The Applicants believe that the next step in the prosecution of this Application should be in the form of a Notice of Allowance and such action is respectfully solicited.

If the undersigned can be of any assistance to the Examiner in addressing issues to advance the application to allowance, please contact the undersigned at the number set forth below.

Respectfully submitted,

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March 29, 2004